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Atty. Docket No. 016243-000150

PTO FAX NO.: 703-305-3014

ATTN: Examiner James Martinell, Ph.D.  
Group Art Unit 1804

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**GROUP 1800 CERTIFICATION OF FACSIMILE TRANSMISSION**

I hereby certify that the following APPELLANT'S REQUEST FOR RECONSIDERATION FOR ENTERING APPEAL BRIEF, and COMMUNICATION with three supplemental pages to brief, in re Application of Richard H. Tullis, Serial No. 08/078,768, filed June 16, 1993, for OLIGONUCLEOTIDE THERAPEUTIC AGENT AND METHODS OF MAKING SAME are being facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

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Dated: January 30, 1996

By: Irene Rodas  
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I hereby certify that this correspondence is being  
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Assistant Commissioner for Patents,  
Washington, D.C. 20231,  
on January 30, 1996

*[Handwritten signature]*  
**PATENT**

TOWNSEND and TOWNSEND and CREW

Attorney Docket No. 016243-000150

By *Jane Rodas*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS

In re application of:

Richard H. Tullis

Serial No.: 08/078,768

Filed: June 16, 1993

For: OLIGONUCLEOTIDE  
THERAPEUTIC AGENT AND  
METHODS OF MAKING SAME

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)  
) Examiner: J. Martinell  
)  
) Art Unit: 1804  
)  
) APPELLANT'S REQUEST FOR  
) RECONSIDERATION FOR ENTERING  
) APPEAL BRIEF

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Appellant requests reconsideration of the Examiner's refusal to enter the Appeal Brief submitted on October 19, 1995. The Examiner's refusal to enter the Brief was made under 37 C.F.R. 1.192 (c).

The Examiner's Communication was mailed on January 19, 1996. This Communication is timely as the Examiner's Communication provided for a one-month response period until February 19, 1996. This request is pursuant to 37 C.F.R. 1.181 (d).

During a telephone conversation with the Examiner on January 25, 1996, the Examiner indicated a willingness to reconsider his position.

Because there is only a one-month period for compliance with refusals to enter purportedly non-conforming appeal briefs, a prompt response by the Examiner is respectfully requested.

PATENT

Richard H. Tullis  
Serial N .: 08/078,768  
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The sole grounds for non-compliance were that certain of the Appellant's arguments, responsive to the breadth rejection under §112, were based upon decisional law developed under §101. There is no outstanding rejection under §101, and Appellant's brief was rejected as not in compliance with the 37 CFR §1.192. The Examiner states:

Appellants present arguments to a rejection which is not in the application. The Brief repeatedly (e.g., pages 21-26, 30 and 31 refers to a utility rejection (i.e., a rejection under 35 U.S.C. 101). There is no rejection under this statute.

Reconsideration is requested. The Brief in no way implies that the outstanding rejection is based upon §101. There are, however, issues under §112 that are analogous to those of §101. This is particularly so in situations where the claims are rejected for undue breadth, as in the instant case.

Breadth rejections arise when an Examiner asserts that the claim does not work for the full scope of the claims. Historically, these workability/op rability rejections have been addressed under both §101 and §112. Representative decisions which exemplify this tension in the law are: *In re Fouche*, 169, 429 (CCPA 1971), *Ex parte Aggarwal*, 23 USPO 2d 1335 (BPA&I 1992) and *In re Brana*, 34 USPO 1437 (Fed Cir. 1995). It is the Appellant's position that simply because a patent examiner rejects claims as non-working under §112, the patent applicant should not be forced to confine his response to the law of §112 without reference to the law developed under §101.

For the record, Appellant is not confused as to the statutory basis for the single remaining rejection. In contrast to the Examiner's position, nowhere in the Brief does Appellant state that there is an outstanding rejection under §101.

In particular, the Examiner has rejected the use of natural oligonucleotides to selectively down regulate protein expression by binding to the coding regions of mRNA because of his belief that they would degrade prior to reaching their target mRNA. The Examiner is respectfully asked to note his own words in the Final Office Action mailed on November 28, 1994. He states:

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Richard H. Tullis  
Serial No.: 08/078,768  
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Claims 64-72 are rejected under 35 U.S.C. §112, first paragraph, as the disclosure is enabling only for claims limited to the preparation and use of stabilized forms of oligonucleotides that are phosphotriesters. ... Applicant's arguments do not address the issue of stability of the oligodeoxyribonucleotides in vivo. ... Thus, applicant's current assertion that any nucleic acid will work is in conflict with applicant's earlier statement.

To the best of appellant's understanding, this rejection has not been withdrawn. In a telephone interview on January 25, the Examiner indicated that the rejection was still maintained.

Appellant strenuously urges that this rejection is a hybrid §101/112 rejection, and he should be allowed to respond in the Brief accordingly. The Examiner's use of the word "work" is the key phrase. Although stated by the Examiner as a pure §112 rejection, the reasoning is based on the Examiner's opinion that non-stabilized oligonucleotides will not *work* in the cell milieu due to nuclease degradation. To prove this is not the case, applicant has relied upon extrinsic evidence, and the Examiner has refused to consider these references. To establish that extrinsic evidence is properly considered in this circumstance, appellant has provided argument at pages 22-23 of the Brief. The decisional law supporting this point arose from hybrid §101/112 rejections. For this reason, and others, Appellant felt obligated to respond to the Examiner's rejection by relying on decisional law addressing both §101 and §112 rejections.

During the telephone interview, the Examiner indicated his willingness to withdraw his refusal to enter the Brief. The Appellant appreciates the Examiner's efforts to resolve this problem. However, the Examiner stated his belief the Appellant's arguments were irrelevant. Reconsideration of this position is also requested.

The difficulties that the Examining Corp has had in dealing with these two statutory sections are well known. Based upon the record before the Board, Appellant would be remiss not to argue the rejection as a hybrid §101/112 rejection regardless of the Examiner's insistence that the rejection is purely under §112. This issue of concern raised by the examiner is purely a semantic distinction of no legal significance. The law controlling §101 and §112 and

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underpinning breadth rejections are identical with regard to whether an invention works as claimed.

Along with this Communication, Appellant submits three supplemental pages for the Brief. Appellant inadvertently failed to include a statement regarding Real Party in Interest and Related Appeals and Interferences. Appellant believes his Brief is now in compliance with the new 1995 rules and requests reconsideration in view of the remarks stated herein.

The Examiner is again reminded that there is a one-month period for compliance accorded non-conforming briefs. A prompt response to this request for reconsideration is respectfully requested.

Respectfully submitted,



Kenneth A. Weber  
Reg. No. 31,677

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Enclosure: Communication w/ three supplemental pages for Brief

I hereby certify that this correspondence is being  
facsimile transmitted to:  
Assistant Commissioner for Patents,  
Washington, D.C. 20231,  
on January 30, 1996

**PATENT**

Attorney Docket No. 016243-000150

TOWNSEND and TOWNSEND and CREW

By *Irene Rodas*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS

In re application of:

Richard H. Tullis

Serial No.: 08/078,768

Filed: June 16, 1993

For: OLIGONUCLEOTIDE  
THERAPEUTIC AGENT AND  
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) Examiner: J. Martinell  
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) Art Unit: 1804  
)  
) COMMUNICATION PURSUANT TO  
) RULE 1.192(c)  
)  
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)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed are three copies of a page to be inserted into Applicant's  
Brief filed on October 19, 1995. The purpose of this submission is to ensure  
compliance with a technical requirement of the Rule 1.192(c).

No fee is thought necessary as the Examiner has indicated a period of  
one month until February 19, 1996, to comply with Rule 1.192. However, if a fee  
is required, the Commissioner is authorized to charge Deposit Account No. 20-  
1430 any fees appropriate to this Communication.

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Respectfully submitted,

*Kenneth A. Weber*  
Kenneth A. Weber  
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**REAL PARTY IN INTEREST:**

U.S.S.N. 08/078,768 is assigned to and owned by Molecular Biosystems, a Delaware Corporation, doing business in San Diego, California.

**RELATED APPEALS AND INTERFERENCES:**

To the best knowledge of the assignee and its legal representatives, there are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. The inventor/appellant is no longer working for the assignee. He is not aware of the status of U.S.S.N. 08/078,768, and has not been consulted with regard to his knowledge of related appeals and interferences.



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